



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 20 1999

The Honorable Craig Thomas
United States Senate
Washington, D.C. 20510-5003

Dear Senator Thomas:

Thank you for your inquiry of July 19, 1999, on behalf of your constituent, Mr. J. Michael Oxley of Laramie, Wyoming, concerning actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation.

The 1997 FDA Modernization Act (PL 105-115) states that "[n]o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients . . ." FDA published a final rule implementing this provision of the law in the Federal Register of August 17, 1998. A copy of this regulation, along with the pre-existing labeling requirements for food treated with ionizing radiation, Title 21 Code of Federal Regulations, § 179, is enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take. The deadline for comments in response to the ANPR was extended to July 19, 1999.

We have forwarded Mr. Oxley's correspondence to the Docket for inclusion in the record. FDA's final approach to labeling of

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~~ANPR~~
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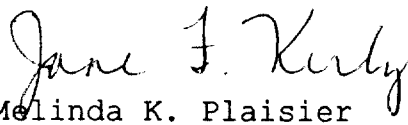
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irradiated foods will take into account all of the data and information received.

Because your constituent may be concerned about irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this information responds to your concerns. If you have further questions about this or any other matter, please do not hesitate to contact us again.

Sincerely,


for Melinda K. Plaisier
Interim Associate Commissioner
for Legislation

Enclosures

cc: Dockets Management Branch
(#98N-1038)

2 July, 1999
J. Michael Oxley
1206 S. 7th St., Apt B
Laramie, WY 82070

The Honorable Craig Thomas
109 Hart Senate Building
Washington, D.C. 20510

Dear Senator Thomas,

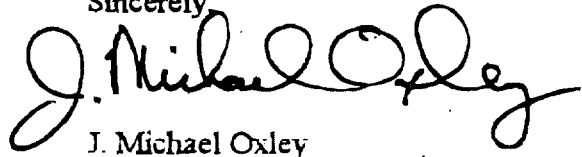
I have recently been made aware of a proposed rule change at the Food and Drug Administration as regards the labeling of irradiated foods. Under pressure from food manufacturers and supporters of the nuclear industry, the FDA is considering a rule that would remove labeling requirements for foods treated with radiation. The public only has until July 18, 1999 to voice its objections to this rule.

The current rule requires that any food treated with radiation during the production process must be labeled with a symbol known as a radura (the international symbol for irradiated foods) and either a statement saying "treated with radiation" or "treated by irradiation." The rule before the FDA would allow manufacturers to sell any and all irradiated foods to the consumer without any mention of the use of radiation during processing. This is bad for consumers.

Despite the fact that the FDA has determined that radiation is safe for food, many consumers, do not want to eat foods treated with radiation. Radiation changes the texture, taste, nutritional value, and chemical composition of foods. Radiation creates a heretofore unseen class of unique radiolytic products that have never been tested for their possible carcinogenic effects on humans. Furthermore, there are no long-term studies on the health effects of irradiated food.

This is a clear-cut issue of individual rights. Consumers have a fundamental right to know what is in their food and how it is processed. Without this knowledge the right to make personal choices is severely eroded. We know what the fat, protein, carbohydrate, and vitamin content is in our food, why should we not know whether our food has been treated with radiation emanating from some of the most deadly substances known to man? Please write a letter to the FDA asking them to continue requiring that irradiated food is clearly labeled.

Sincerely,



J. Michael Oxley

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